

REMARKS

Rejection of claims 1-17 and 19-37 under 35 U.S.C. § 102(b)

Claims 1-17 and 19-37 were rejected as anticipated by EP 0 521 562. For the following reasons, the applicant respectfully traverses.

In brief, EP 0 521 562 cannot anticipate the present claims because it does not contain an enabling disclosure. It is settled law that a prior art reference cannot anticipate if it is not enabling or enabled. *E.g.*, MPEP § 2121.01.

EP 0 521 562 discloses dispersions of reversed vesicles, prepared from different types of vesicle-forming compounds and apolar carrier materials. Although the document in column 12, lines 55-56, mentions that the non-polar excipient(s) is to be removed to obtain an instant product, there is no teaching or even suggestion of how to do it.

EP 0 521 562 teaches a number of different surfactants (non-ionic, anionic, cationic, amphoteric and other suitable ones) in combination with different non-polar vehicles, and lipophilic and hydrophilic stabilising factors were mentioned to be useful for the preparation of stable dispersions of reversed vesicles. Despite the fact that in some of these examples a volatile silicon oil was used as the non-polar vehicle, there are no teachings as to how to remove such vehicle.

EP 0 521 562 disclosed stable dispersions of reversed vesicles in a non-polar phase, but neither it nor other art available on the priority date of the present application taught how to remove the external phase. Contrary to vesicular systems known at the time of filing the present application, the external phase consisted of a non-polar and not a polar vehicle. Conventional techniques for removing a polar vehicle from vesicular systems cannot be applied without further experimentation of reversed vesicular systems. Furthermore, the ordinary artisan would not know what would happen to the physical structure of the vesicles on removing the non-polar vehicle and would not know about the properties of the residue after removing the non-polar phase.

In conclusion, therefore, because EP 0 521 562 is a non-enabling reference, it cannot anticipate the present claims. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection of claims 1-17 and 19-37 under 35 U.S.C. § 103

Claims 1-17 and 19-37 were rejected as obvious over EP 0 521 562 alone or in combination with EP 0 678 295, EP 0 159 237, GB 2002319, JP 051 94253 each alone or in combination. For the following reasons, the applicants respectfully traverse.

EP 0 521 526 relates - amongst other things - to stable dispersions of reversed vesicles in a biodegradable oil (glycerol tri-esters of higher saturated fatty acids having 10-30 carbon atoms, such as glyceryltrilaurate and hydrogenated castor oil, and vegetable oils, such as coconut oil and peanut oil). However, as noted above, EP 0 521 526 does not teach or suggest a method of making the instantly claimed powder of reversed vesicles.

The cited secondary references do not compensate for the deficiency of EP 0 521 562.

EP 0 678 295 relates to a completely different issue than EP 0 521 562 and the present invention. EP 0 678 295 is concerned with how to load an active principal into liposomes. It is not concerned with increasing the amount of the liposome vehicle, let alone reversed vesicles in a non-polar vehicle. EP 0 678 295 relates to providing a method to manufacture liposomes (vesicles in a polar vehicle) exhibiting a high drug content by the formation of a drug-phospholipid complex in an organic solvent first, removing the organic solvent, and then adding the polar vehicle to the residue thus obtained.

EP 0 159 237 is also not related to issue of the present invention or EP 0 521 562. EP 0 159 237 relates to oral oil-in-water emulsions and seeks to eliminate inherent disadvantages of oil-in-water emulsions (such as limited shelf life, especially after starting to take the medication), inaccuracy of dosing, incompatibility of active ingredients, heat-sensitivity and prone to microbial attack, by distributing the emulsion over single-dose packs and subsequently freeze-drying these to provide single-dose units in solid form. These units can be administered orally with or without water. EP 0 159 237 does not relate to vesicular systems at all and therefore cannot compensate for the deficiencies of EP 0 159 237.

GB 2002319, aims at providing a solution for the short shelf life of liposomes (vesicles in a polar vehicle) by providing a process for the dehydration of the liposomes - by lyophilisation under the addition of a hydrophilic compound - to obtain a powder which can be stored for a longer period and from which, and with an aqueous medium, a liposome dispersion can be re-constituted. However, during lyophilisation about 30% of the liposomes were destroyed and therefore there is a decrease in percent yield of liposomes. As GB 2002319 deals with liposomes

in a polar medium (rather than reversed vesicles in a non-polar medium) and teachings a loss of 30% of the liposomes, one of ordinary skill in the art seeking to improve the percent yield of (reversed) vesicles in a non-polar vehicle would not be inclined to apply the teachings of this document to this problem.

JP-5194253 relates to the preparation of a reversed micelles containing solution as a first step in the preparation of polymer microcapsules. There is no mention (explicit or implied) of increasing the percent yield of micelles/microcapsules. Therefore this document does not contribute any teachings or suggestions of how to prepare the instantly claimed reversed vesicles (or methods of preparing them).

Thus, none of the secondary art compensate for the deficiencies of the primary reference by providing a teaching or suggestion of a method for obtaining the instantly claimed powder of reversed vesicles or, therefore, the reversed vesicles themselves.

Furthermore, the Patent Office has still not provided any evidence or scientifically based reason countering the unexpected results of the presently claimed method and consequent unexpected property of the presently claimed reversed vesicles and powders. There is simply no teaching or suggestion or other evidence from which one of ordinary skill in the art could have expected that the presently claimed method would produce a powder of reversed vesicles that when dispersed in a biodegradable oil would result in a percent of reversed vesicles that is greater than the percent resulting from preparation of the reversed vesicles directly in the biodegradable oil. On this basis alone the present claims are non-obvious.

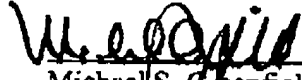
In summary, the primary reference fails to teach the presently claimed powder of reversed vesicles or the claimed method of making them, and the secondary art does not compensate for this deficiency because it addresses unrelated issues relating to different systems. Furthermore, the presently claimed invention possesses an unexpected property.

In view of the foregoing, therefore, the applicants respectfully request reconsideration and withdrawal of this § 103 rejection.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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